



May 10, 2004

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane,  
Room 1061  
Rockville, MD 20852

NATIONAL  
FOOD  
PROCESSORS  
ASSOCIATION

**RE: Docket No. 2004N-0133, Electronic Records, Electronic Signatures; Public Meeting**

Dear Sir/Madam:

The National Food Processors Association (NFPA) welcomes this opportunity to participate in the public hearing and comment on the above referenced Electronic Records, Electronic Signatures regulation. NFPA is committed to the important goal of promoting and protecting public health and is striving to work closely with the Food and Drug Administration (FDA) as regulations are being developed to respond appropriately to security measures without undue disruption to industry operations.

NFPA is the voice of the \$500 billion food processing industry on scientific and public policy issues involving food safety, food security, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications and crisis management support for the Association's U.S. and international members. NFPA members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks and juices, or provide supplies and services to food manufacturers. NFPA members import ingredients for further processing and export finished processed food products globally and will, consequently, be affected by this rulemaking.

The following abstract is submitted on behalf of the NFPA food industry members. NFPA has had numerous discussions with the FDA, via the Industry Coalition and directly with Center for Food Safety and Nutrition (CFSAN) representatives over the past three years in order to increase

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the awareness of issues in compliance within the food industry. This new scope and application guidance reflects a workable approach to the food industry. NFPA members agree with the risk-based approach to compliance as it reflects the current approach used in the juice and seafood operations that employ Hazard Analysis and Critical Control Points (HACCP). By applying a risk-based approach, the industry can focus its attention on the most critical food safety records/data. This allows different records to be handled according to risk rather than all records being given equal weight. For example, shipping and distribution records versus thermal process records. One way to assign levels of risk would be to first focus on those products that present greatest risk to the consumer (e.g. Low Acid Canned Foods versus cereal products) followed by a focus on those electronic data records that are most associated with assuring the safety of the product. This approach will also allow companies to plan out their capital spending in phases by addressing the high-risk areas first and then moving on down the list. In some cases, there may not be a need to do anything more than what is currently done because there is no risk to food safety or the public health.

Integrating risk based processes into Part 11 and computer system validation, will take time and this reality should be clearly recognized in FDA's plans for future guidance, enforcement and internal training. NFPA's members strongly support the open dialogue with FDA and have a vested interest in developing sound approaches to managing and maintaining electronic documents.

Sincerely,

A handwritten signature in black ink, appearing to read 'Sia Economides', written in a cursive style.

Sia Economides  
Center Director  
Center for the Development of Research  
Policy & New Technology